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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Masaru Kimura

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FRISHAUF, HOLTZ, GOODMAN & CHICK, PC
220 Fifth Avenue
16TH Floor
NEW YORK, NY 10001-7708

EXAMINER

SZNAIDMAN, MARCOS L

ART UNIT

PAPER NUMBER

1611

MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,757	Applicant(s) KIMURA ET AL.	
	Examiner MARCOS SZNAIDMAN	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6,12,13 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,12,13 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's reply filed on April 16, 2008.

Status of Claims

Amendment of claim 1 and cancellation of claims 4, 7-11, and 14-16 is acknowledged.

Claims 1, 3, 5-6, 12-13, and 17-19 are currently pending and are the subject of this office action.

Claims 1, 3, 5-6, 12-13, and 17-19 are currently under examination.

Priority

The present application is a 371 of PCT/JP05/06017 filed on 03/30/2005, and claims priority to foreign application: JAPAN 2004-107084 filed on 03/31/2004.

Response to Arguments

This is in response to applicant's arguments, filed on April 16, 2008.

Claims rejected under 35 USC 112, second paragraph.

Due to applicant's cancellation of claims 4, 10-11, and 14-16, the 112 second rejection is now moot.

Rejection under 35 USC 112, second paragraph is withdrawn.

Claims rejected under 35 USC 102 (b).

Applicant's arguments have been fully considered but are not persuasive.

Applicant amended claim 1 replacing the broad term "organic peroxide" with a more specific term: "a peroxide of an imidazole derivative" in order to overcome the 102(b) rejection based on Akiya et. al. (JAPAN 2002-047208, cited in the previous office action), since Akiya et. al. do not teach "peroxide imidazole derivatives". However, claim 1 recites "...comprising a compound selected from the group consisting of a peroxide of an imidazole derivative and a chemiluminescent". In other words, claim 1 still recites a chemiluminescent compound that is taught by Akiya et. al., hence claim 1 and its dependent claims 3, 6, 13 and 17 are still anticipated by Akiya et. al.

Rejection under 35 USC 102(b)) is maintained.

Claims rejected under 35 USC 103 (a)

Applicant's arguments have been fully considered and are persuasive. Therefore the rejection is withdrawn. However, upon further consideration, a new ground of rejection is made.

A new USC 103 (a) rejection is applied.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 19, which depends from claim 18, which depends from claim 17, recites the same limitations as claim 17.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6, 13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Akiya et. al. (JAPAN 2002-047208, cited in previous office action) as evidenced by Di Mascio et. al. (J. Am. Chem. Soc. (1989) 111:2909-2914).

Claims 1, 3, 6, and 13 recite a method of treating cancer or inducing sudden death of cancer cells by administering to a patient in need thereof a pharmaceutically effective amount of a heat and/or singlet oxygen-generating agent comprising a compound selected from the group consisting of a peroxide of an imidazole derivative and a chemiluminescent compound (dioxetane compound in claims 6 and 13).

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For claims 1, 3, 6 and 13 Akiya teaches a method of treating cancer by administering to a patient a peroxide capable of generating a singlet oxygen (see abstract and paragraphs [0004] and [0005]). Among the peroxides capable of generating a singlet oxygen they teach the structures of some dioxetanes (cyclic peroxides, see Formula 1 and Formula 2 in paragraph [0009]). Although Akiya et. al. do not mention that these compounds are chemiluminescent, this is an inherent property of the compounds of formula 1 and 2 as evidenced by Di Mascio et. al. Di Mascio et. al. teach that compound NDPO₂ (which corresponds to structure of Formula 2 of Akiya et. al., when R₁ and R₂ are –CH₂CH₂COOH) is chemiluminescent and generates singlet oxygen (see abstract and introduction)

Claim 17 recites the same limitations of claim 1, wherein the cancer is selected from the group consisting of: liver cancer, lung cancer, stomach cancer, large intestine cancer, skin cancer and uterine cancer.

For claim 17 Akiya et al. further teaches that the types of cancer to be treated are: liver cancer, lung cancer and pancreatic cancer (see last sentence of paragraph [0005]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiya et. al. (JAPAN 2002-047208, cited in previous office action) further in view of Frandsen et. al. (Acta Chem. Scan. (1991) 45:627-631).

Claim 5 and 12 recite the same limitations of claims 1 and 3 respectively, wherein the compound that is capable of generating a singlet oxygen is the peroxide of an imidazole derivative.

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Akiya et al., teach all the limitations of claims 5 and 12, except for the use of a peroxide that is an imidazole derivative. However, Frandsen et. al. teach that imidazole peroxides (the peroxide of fenflumizole in particular, compound 9) are capable of generating a singlet oxygen (see abstract and page 628, right column under “Thermal degradation of hydroperoxide 9 in ethanol”).

Since Akiya et. al. teach that cancer can be treated with a peroxide capable of generating singlet oxygen upon decomposition, and since Frandsen teaches that imidazole peroxides are capable of generating singlet oxygen upon decomposition, at the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to substitute one functional equivalence (any peroxide capable of generating a singlet oxygen) for another (imidazole peroxide) with an expectation of success, since the prior art establishes that both function in a similar manner, thus resulting in the practice of claims 5 and 12 with a reasonable expectation of success.

Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiya et. al. (JAPAN 2002-047208, cited in previous office action) in view of Frandsen et. al. (Acta Chem. Scan. (1991) 45:627-631), and further in view of Kimura et. al. (ITE Letters on Batteries, New Technologies and Medicine (2000), 1:418-421, cited by applicant, cite in previous office action) or Tsunenaga et. al. (ITE Letters on Batteries, New Technologies and Medicine (2003), 4:633-638, cited by applicant).

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Claims 18-19 recite the same limitations as claim 17, wherein the compound that generates the singlet oxygen, is selected from the group consisting of the structures depicted in claim 18.

Akiya et. al. teaches all the limitations of claim 18 and 19, except for the compounds listed in claim 18. However Kimura et. al. and Tsunenaga et. al. teach the imidazole peroxide corresponding to the first structure of claim 18 (the hydroperoxide of 2-(2-hydroxyphenyl)-4,5-diphenylimidazole) (see Kimura et. al. compound 2b, page 419 under the result and discussion section, last paragraph, or Tsunenaga et. al. ,compound 2b, abstract). Kimura et. al or Tsunegaga et. al. do not teach that the imidazole peroxide of 2-(2-hydroxyphenyl)-4,5-diphenylimidazole generates singlet oxygen. However, Frandsen et. al. teach that imidazole peroxides (the peroxide of fenflumizole in particular, compound 9) are capable of generating a singlet oxygen (see abstract and page 628, right column under "Thermal degradation of hydroperoxide 9 in ethanol").

Since Akiya et. al. teach that cancer can be treated with a peroxide capable of generating singlet oxygen upon decomposition, and since Kimura et. al. or Tsunenaga et. al teach the imidazole peroxide of 2-(2-hydroxyphenyl)-4,5-diphenylimidazole, and since Frandsen teaches that imidazole peroxides are capable of generating singlet oxygen upon decomposition, at the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to substitute one functional equivalence (any peroxide capable of generating a singlet oxygen) for another (an imidazole peroxide in general or the imidazole peroxide of 2-(2-hydroxyphenyl)-4,5-diphenylimidazole in particular) with an expectation of success, since the prior art

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establishes that both function in a similar manner, thus resulting in the practice of claims 18 and 19 with a reasonable expectation of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/MARCOS SZNAIDMAN/

Examiner, Art Unit 1611

August 13, 2008

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611